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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,773	06/20/2003	Martin Grunwald	100727-50/Heracus 402-KGB	6455
27384	7590	12/14/2006	EXAMINER	
NORRIS, MCLAUGHLIN & MARCUS, PA 875 THIRD AVENUE 18TH FLOOR NEW YORK, NY 10022			JASTRZAB, KRISANNE MARIE	
			ART UNIT	PAPER NUMBER
			1744	

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/600,773

Applicant(s)

GRUNWALD ET AL.

Examiner

Krisanne Jastrzab

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-4, 6, 9 and 13-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 2, this claim is found to be vague and indefinite because it is unclear as to what is actually being claimed. It is unclear whether the impression materials are provided as two components for sterilization, if a cross-linking step is being claimed and if so, whether or not it is before or after sterilization, or if two-component, cross-linked elastomeric material is being provided for sterilization. Clarification is required.

With respect to claim 3, this claim is still found to be vague and indefinite because it is also unclear as to what further method limitations are being claimed. Clarification is required.

With respect to claim 4, this claim is found to be vague and indefinite because it is unclear as to what limitations would be required by the language "handled as a system". Clarification is required.

With respect to claim 6, "additional cross-linking silicon impression material" lacks proper antecedent basis and it is unclear as to whether this is additional material being sterilized or specification of the type of previously claimed impression material.

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With respect to claim 9, the recitation of "treated" lacks proper antecedent basis and is found to be vague and indefinite because it is unclear as to what would actually constitute "treated".

With respect to claims 13-15, these claims are found to be vague and indefinite because they fail to properly further limit the claims from which they depend. These claims merely recite the intended use of the materials to be sterilized by the claimed invention, and such recitation fails to properly require any further method limitations for sterilization.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 8-9, 11-15 and 17-18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Larson U.S. patent No. 5,540,876.

Larson teaches substantially the invention as claimed, namely the radiation sterilization of polymeric impression material for dental impressions. It is taught the the polymer can be a blend and include polysiloxanes, and that the material can be treated while pre-packaged, with gamm radiation to achieve sterilization. See column 1, lines 5-15, column 2, lines 25-45 and 60-68 and column 3, lines 15-30, column 7, Example 12, and column 9, lines 25-29.

Claims 1-5, 8-9, 11-15 and 17-18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Olsen U.S. patent No. 4,952,618.

Olsen teaches gamma sterilization of an elastomeric polymer for medical use applications wherein the polymer composition can include polyacrylates and alginate and is preferably sterilized with gamma radiation between 2.5 and 4 Mrads. The polymer can be formed by blending two powder components. Also, the patent teaches sterilizing the polymers with their backing materials as a system. See the abstract, column 2, lines 20-25, column 3, lines 15-35, column 4, lines 2-3 and lines 19-35, column 6, lines 63-68 and columns 7 and 8, lines 1-10 of each.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Larson or Olsen as applied to claim 1 above.

Both references teach sterilization of the polymer material in a packaged state ready for medical use and it would have been obvious to one of ordinary skill in the art to include any components required for application of the polymer within the same package because the efficacy of gamma sterilization of packaged articles for a myriad of uses is well recognized and conventional in the art.

Claims 6-7 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Larson or Olsen as applied to claim 1 above, and further in view of Amos U.S. patent No. 5,804,620.

Amos teaches that it is known in the art to include polysiloxanes as an additive in polymers used for medical applications which will be sterilized with gamma radiation because such siloxanes enhance the integrity of the polymers following radiation treatment. Amos teaches the presence of polysiloxanes in an amount around 3% with greater amounts also taught as effective. See the abstract, column 1, lines 10-23, column 2, lines 8-25, column 3, lines 18-27, column 4, lines 14-26, column 5, lines 1-20 and the claims.

It would have been obvious to one of ordinary skill in the art to include polysiloxanes in the polymers of either Larson or Olsen for the recognized purpose of enhancing the integrity of those polymers following sterilization with gamma radiation.

Response to Arguments

Applicant's arguments filed 9/27/2006 have been fully considered but they are not fully persuasive.

Applicant argues that Larson teaches a thermoplastic which is not an elastomer, however, the Examiner would point out that Larson's examples all show increased elasticity of the polymer following gamma sterilization and being a thermoplastic does not preclude as being an elastomer.

Applicant's arguments with respect to claims 2-18 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

The indicated allowability of claim 7 is withdrawn in view of the newly discovered reference(s) to Olsen and Amos. Rejections based on the newly cited reference(s) are recited above.

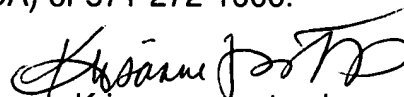
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krisanne Jastrzab whose telephone number is 571-272-1279. The examiner can normally be reached on Mon.-Thurs. 6:00am-4:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Krisanne Jastrzab
Primary Examiner
Art Unit 1744

December 11, 2006